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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mehdi Ganjeizadeh
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,781	SOULARD, PATRICIA	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-67 are pending.

Applicants are advised that claims 61-67 are directed to the use of a compound, which is non-statutory subject matter, i.e. neither a product nor a method. For restriction purposes, it will be assumed that the term "the use of X" is "a method of use of X".

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III.	Claims 1-11, 19, 53, drawn in part to a polypeptide having phosphodiesterase activity wherein said polypeptide comprises the amino acid sequence of SEQ ID NO: 1-3, respectively, classified in class 435, subclass 199 (i.e. Group I is drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, Group II is drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, etc.).
IV-V.	Claims 12-13, 19, 53, drawn in part to a human PDE7A1 and PDE7A2, respectively, classified in class 435, subclass 199 (i.e. Group IV is drawn to a human PDE7A1, and Group V is drawn to a human PDE7A2).
VI-VIII.	Claims 14-29, 33, 54-55, drawn in part to polynucleotides encoding polypeptides comprising the amino acid sequence of SEQ ID NO: 1-3, vectors, host cells and a method of recombinantly producing polypeptides comprising the amino acid sequences of SEQ ID NO: 1-3, respectively, classified in class 536, subclass 23.2.

IX-X.	Claims 14-29, 33, 54-55, drawn in part to polynucleotides, vectors, host cells and a method of recombinantly producing a human PDE7A1 and PDE7A2, respectively classified in class 536, subclass 23.2.
XI-XIII.	Claims 30-32, drawn in part to a transgenic animal comprising polynucleotides encoding polypeptides comprising the amino acid sequence of SEQ ID NO: 1-3, respectively, classified in class 800, subclass 8.
XIV-XV.	Claims 30-32, drawn in part to a transgenic animal comprising polynucleotides encoding a human PDE7A1 and PDE7A2, respectively, classified in class 800, subclass 8.
XVI.	Claims 34-37, drawn in part to a method for in vitro screening of a compound which inhibits phosphodiesterase activity with a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, classified in class 435, subclass 19.
XVII-XVIII.	Claims 34, 36-37, drawn in part to a method for in vitro screening of a compound which inhibits phosphodiesterase activity with a polypeptide comprising the amino acid sequence of SEQ ID NO: 2-3, respectively, classified in class 435, subclass 19.
XIX-XX.	Claims 34, 36-37, drawn in part to a method for in vitro screening of a compound which inhibits phosphodiesterase activity with a human PDE7A1 and PDE7A2, respectively, classified in class 435, subclass 19.
XXI-XXIII.	Claims 38-52, drawn in part to a method for in vitro screening of a compound which inhibits phosphodiesterase activity with a host cell comprising a polynucleotide encoding a polypeptide comprising the

amino acid sequence of SEQ ID NO: 1-3, respectively, classified in class 435, subclass 6.

XXIV-XXV. Claims 38-52, drawn in part to a method for in vitro screening of a compound which inhibits phosphodiesterase activity with a host cell comprising a polynucleotide encoding a human PDE7A1 and PDE7A2, respectively, classified in class 435, subclass 6.

XXVI-XXVIII. Claim 56, drawn in part to a method for selecting a compound which inhibits PDE7 phosphodiesterase activity by isolating a compound which inhibits phosphodiesterase activity in a polypeptide comprising the amino acid sequence of SEQ ID NO: 1-3, and testing said compound with a cell that comprises a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 1-3, respectively, classified in class 435, subclass 6.

XXIX-XXX. Claim 56, drawn in part to a method for selecting a compound which inhibits PDE7 phosphodiesterase activity by isolating a compound which inhibits phosphodiesterase activity in a human PDE7A1 and PDE7A2, and testing said compound with a cell that comprises a polynucleotide encoding a human PDE7A1 and PDE7A2, respectively, classified in class 435, subclass 6.

XXXI-XXXIII. Claims 57-59, drawn in part to a method for selecting a compound which inhibits PDE7 phosphodiesterase activity by isolating a compound which inhibits phosphodiesterase activity in a polypeptide comprising the amino acid sequence of SEQ ID NO: 1-3, and testing if said compound

inhibits other PDE enzymes, respectively, classified in class 435, subclass 19.

XXXIV-XXXV. Claims 57-59, drawn in part to a method for selecting a compound which inhibits PDE7 phosphodiesterase activity by isolating a compound which inhibits phosphodiesterase activity in a human PDE7A1 and PDE7A2, and testing if said compound inhibits other PDE enzymes, respectively, classified in class 435, subclass 19.

XXXVI. Claim 60, drawn to an inhibitor of PDE7 phosphodiesterase activity, classification unknown as the structure of the inhibitor is unknown.

XXXVII. Claims 61-67, drawn to a method of use for an inhibitor of PDE7 phosphodiesterase activity for the treatment, diagnosis or surgery of humans or animals, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-V, VI-X, XI-XV, and XXXI each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. Each of the polynucleotides in Groups VI-X comprises an unrelated nucleic acid sequence, the transgenic animal in Groups XI-XV is a multicellular organism whereas the proteins of Groups I-V each comprise an unrelated amino acid sequence. The inhibitor of Group XXXI comprises an undefined agent which can be chemical or a biological compound. The polynucleotides in Groups VI-X have other uses besides encoding the proteins of Groups I-V or being introduced in the transgenic animals of Groups XI-XV, such as a hybridization probe or in gene therapy. The transgenic animals of Groups XI-XV can have other uses such as in vivo testing besides manufacturing the proteins of Groups I-V. Further, the proteins of Groups I-V can be prepared by processes which are materially different from recombinant DNA expression of Groups VI-X or

expression in the transgenic non-human animals of Groups XI-XV, such as by chemical synthesis, or by isolation and purification from natural sources.

3. Inventions I-V and XVI-XX, XXVI-XXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Inventions I-V can be used to elicit antibodies as well as in the methods of Inventions XVI-XX, XXVI-XXXV.

4. Inventions VI-X and XXI-XXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells of Inventions VI-X can be used to recombinantly produce the proteins of Inventions VI-X as well as in the methods of Inventions XXI-XXV.

5. Inventions XXXVI, XVI-XXXV, and XXXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, if the inhibitor of Invention XXXVI is a protein, it can be used to elicit antibodies as well as in the methods of Inventions XVI-XXXV, or XXXVII.

6. Inventions I-X and XXXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides and polynucleotides of Inventions I-X are neither used nor made by the method of Invention XXXVII.

7. The methods of Groups XXVI-XXX are related to the methods of Groups XVI-XXV by virtue of using compounds which have been screened with the methods of Groups XVI and testing said compounds using the steps in the methods of Groups XXI-XXV. However they are distinct inventions because the methods of Groups XXVI-XXX comprise different steps and produce different results from those in the methods of Groups XVI-XXV.

8. Inventions XVI-XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions XVI-XX use the polypeptides of Groups I-V to screen for inhibitors whereas the methods of Inventions XXI-XXV use the host cells of Groups VI-X to screen for inhibitors.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

10. The terms "human PDE7A1" and "human PDE7A2" are generic terms which can potentially encompass more than one protein with different amino acid sequences. If Applicants elect any of the groups related to human PDE7A1 or PDE7A2 (protein, DNA, transgenic animal or methods), a supplemental restriction may be required if the corresponding claims are amended to refer to more than one human PDE7A1 or PDE7A2 (i.e. more than one sequence). It is noted that the Examiner has not been able to determine if any of the polypeptides of SEQ ID NO: 1-3 is a human PDE7A1 or PDE7A2. If in response to this Office Action, Applicants elect any of the groups related to the polypeptides of SEQ ID NO: 1-3 (protein, DNA, transgenic animal or methods) and indicate that the polypeptide associated with the elected Group is a human PDE7A1 or PDE7A2, the Examiner will rejoin those claims of the corresponding Group which are related to either human PDE7A1 or PDE7A2. For example, if Applicants elect Group II (claims 1-11, 19, 53 directed in part to the polypeptide of SEQ ID NO: 2) and indicate that

the polypeptide of SEQ ID NO: 2 encodes a human PDE7A1, the Examiner will rejoin claims 12-13 of Group V and examine these claims to the extent they relate to the claimed invention.

11. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 30, 2004

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600